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REPORT
101-390

IMMUNIZATION REAUTHORIZATION ACT OF 1990

JULY 24 (legislative day, JULY 10), 1990.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 2629]

The Committee on Labor and Human Resources, to which was referred the bill (S. 2629), to amend the Public Health Service Act to extend the immunization program for vaccine-preventable diseases, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommend that the bill as amended do pass.

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I. SUMMARY OF THE BILL

The bill amends Title III of the Public Health Service Act to reauthorize the Centers for Disease Control's immunization programs for $200 million in fiscal year 1991 and such sums as may be necessary through 1995. The legislation also reauthorizes funds for the establishment of a six-month vaccine stockpile for $5 million in fiscal year 1991 and such sums as may be necessary through 1995. The bill adds a new section to establish immunization demonstration projects for the development, demonstration, and evaluation of methods for the screening, referral, and immunization of children

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up to 24 months of age. These demonstration projects would be authorized, in addition to the funds authorized above, for such sums as necessary for fiscal years 1991 to 1993.

S. 2629 also amends Title XXI of the Public Health Service Act to reauthorize the National Vaccine Program, administered through the Office of the Assistant Secretary for Health. The bill reauthorizes the National Vaccine Program through 1995, authorizing $4 million for program operations and $30 million for supplementing the funds of other Federal agencies in accordance with the goals of the National Vaccine Plan.

II. Background and Need for the Legislation

Immunization for preventable diseases has proven to be one of the most successful and cost-effective methods employed in preventive medicine. The development of the measles vaccine, for example, has succeeded in reducing the incidence of measles by over 90 percent, with the number of deaths as a result of measles declining from 500 annually prior to the development of a vaccine to none in 1984. Despite a sharp resurgence of measles, the number of deaths due to measles in 1989 remains at less than 10 percent of the pre-vaccine level. This success in reducing the incidence of measles translates into an estimated cost savings of $500 million per year (a benefit-cost ratio of 14:1). Other vaccines, such as for polio, diphtheria-pertusis-tetanus, and hepatitis B also have been successful and cost-effective in reducing the rates of disease. Despite these successes, however, there remain problems resulting from low immunization levels among some populations, a major outbreak of measles, and a high incidence of hepatitis B.

The Federal government's role in supporting immunization programs has developed since the 1950's when the polio vaccine was discovered, and the program has grown with the development of new vaccines and the expansion of the program beyond immunization grants for childhood diseases only. The Federal immunization programs administered by the Centers for Disease Control currently provides grants to states for the purchase of vaccines; state operational costs; parental and patient notification materials; measles outbreak control; and Hepatitis B screening. In addition, the CDC receives funds for direct program operations and the reporting of adverse events resulting from vaccines.

The public health sector's vaccine efforts are facing particular difficulties as a result of the current measles epidemics. By 1983, the number of measles cases reported to CDC had decreased to nearly 1,500. The lack of immunization in many pre-school children and the questioned effectiveness of a single dose of vaccine, however, has led to a nationwide epidemic, with over 16,000 cases and 40 deaths in 1989. If current trends continue, 30,000 cases and over 100 deaths could occur in 1990. To increase the effectiveness of the measles vaccine, the CDC Advisory Committee on Immunization Practices and the American Academy of Pediatrics have recommended providing children with a second dose of the vaccine.

The 1987 Public Health Service Amendments provided authorization to enable a 6 month stockpile of vaccines to prevent disruption of the domestic vaccine supply. Although significant progress has

been made in achieving this goal, the stockpile remains 10 percent below the 6 month supply level.

The National Vaccine Program was established in 1986 and is directed to coordinate and provide direction to the five participating Federal agencies in vaccine programs in seven areas: research; development; safety and efficacy testing; production and procurement; distribution and use; and evaluating the need for, effectiveness of, and adverse effects of vaccine and immunization activities. In addition, the National Vaccine Program is intended to coordinate governmental and non-governmental immunization activities and is authorized to use additional funds to supplement the available funds of the participating agencies. The Director of the National Vaccine Program is required to establish an annual National Vaccine Plan reporting on these functions.

III. Text of the Bill as Reported

[S. 2629; 101st Cong., 2d Sess.]

A BILL To amend the Public Health Service Act to extend the immunization program for vaccine-preventable diseases, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Immunization Program Reauthorization Act of 1990".

SEC. 2. EXTENSION OF IMMUNIZATION GRANT PROGRAM.

Section 371(j)(1) of the Public Health Service Act (42 U.S.C. 247B(j)(1)) is amended—

(1) in subparagraph (A), by striking "there are authorized" and all that follows in the first sentence and inserting the following: "there are authorized to be appropriated $200,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995."; and

(2) in subparagraph (B), by striking "after the date" and all that follows and inserting the following: "after October 1, 1990, there are authorized to be appropriated such sums as may be necessary.".

SEC. 3. SUPPLY OF VACCINES.

(a) In General.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall acquire and maintain a supply of vaccines sufficient to provide vaccinations throughout a 6-month period.

(b) Authorization of Appropriations.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.

SEC. 4. EXTENSION OF NATIONAL VACCINE PROGRAM.

Section 2106 of the Public Health Service Act (42 U.S.C. 300aa-6) is amended—

(1) in subsection (a), by striking "there are authorized" and all that follows and inserting the following: "there are authorized to be appropriated $4,000,000 for fiscal year 1991, and such

sums as may be necessary for each of the fiscal years 1992 through 1995."; and

(2) in subsection (b), by striking "there are authorized" and all that follows and inserting the following: "there are authorized to be appropriated $30,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.".

SEC. 5. IMMUNIZATION DEMONSTRATION PROJECTS.

Part B of title III of the Public Health Service Act is amended by inserting after section 317A (42 U.S.C. 247b-1) the following new section:

"SEC. 317B. IMMUNIZATION DEMONSTRATION PROJECTS.

"(a) GRANTS AND CONTRACTS.—

"(1) IN GENERAL.—The Secretary, acting through the Centers for Disease Control, may make grants to public and private nonprofit entities and enter into contracts with private entities to establish and support projects for the development, demonstration and evaluation of methods for the screening, referral and immunization of children up to 24 months of age against vaccine-preventable diseases and for the dissemination of information concerning such methods to the health and allied health professions.

"(2) ADDITIONAL RESOURCES.—The Secretary shall utilize additional resources to implement projects under this section that are designed to make more effective use of immunization grant resources to immunize at least 90 percent of all children by the time they reach 24 months of age.

"(3) COORDINATION.—Activities conducted under projects receiving assistance under this section shall be coordinated with Federal, State, local and regional health and immunization entities that conduct activities under section 317.

"(b) TYPE OF PROJECTS.—Projects that may receive assistance under this section shall include programs that emphasize the development and demonstration of new and improved—

"(1) methods of immunizing children up to 2 years of age who are part of low-income and high-risk populations and geographic areas against vaccine-preventable diseases;

"(2) methods of screening, early intervention, and referral for immunization against childhood disease;

"(3) methods of measuring actual immunization coverage levels in defined populations to better identify unvaccinated children and to strengthen surveillance in areas of low coverage;

"(4) methods of tracking patient data and recordkeeping with the use of an automated patient management information system; and

"(5) methods of dissemination of information to health and allied health professionals and to low-income and high-risk populations concerning the importance of immunization of children up to 24 months of age at the earliest medically appropriate time, and concerning possible adverse reactions associated with immunizations.

"(c) AUTHORIZATION OF APPROPRIATIONS.—In addition to such sums as are authorized to be appropriated under section 317, there are authorized to be appropriated such additional sums as may be necessary for each of the fiscal years 1991 through 1993 for immunization demonstration project grants and contracts under this section.".

IV. COMMITTEE VIEWS

The Committee is particularly concerned about the current measles epidemic and the availability of sufficient funds for appropriate immunization and outbreak control. The Committee authorization for the immunization programs, $200 million for fiscal year 1991 and such sums as may be necessary through 1995, is intended to be sufficient to provide for the Federal share of implementing the double dose of measles vaccine and for expanding measles outbreak control efforts in addition to the immunization program's current activities. These steps are essential in the public health sector's continued fight against the current measles epidemic.

The reauthorization for fiscal year 1991 also includes language to authorize appropriations of such sums as may be necessary to provide for new vaccines if they are recommended after the date of authorization. In particular, the Committee is aware that, in the near future, vaccines may be developed and recommended for immunizing against chicken pox and the infant transmission of hepatitis B.

The Committee is also concerned with the low immunization levels among pre-school children in many areas. Many children do not receive immunizations until they are required for school entry despite recommendations for the vaccination at an earlier age, and therefore these pre-schoolers are at particularly high-risk for many preventable communicable diseases. Language in this reauthorization bill establishes demonstration projects to support the development, demonstration and evaluation of methods for the screening, referral and immunization of children up to 24 months of age against vaccine-preventable diseases. These demonstration projects are intended to target children who are low-income and in high-risk populations or geographic areas in order to more effectively increase the immunization levels among children under the age of 2 years. The high incidence of measles among unvaccinated preschool children reinforces the critical importance of increasing the immunization levels among pre-schoolers.

The Committee recognizes the importance of maintaining an adequate inventory of vaccines to protect against an interruption of the domestic supply of vaccines. The vaccine stockpile was first authorized in the Public Health Service Act of 1987. Although significant progress has been made toward achieving the goal of a six month stockpile of vaccines, the stockpile remains nearly 10 percent below that level. The implementation of the recommended second dose of measles vaccine will also increase the need for additional measles vaccines for the stockpile. The legislation, therefore, authorizes $5 million in fiscal year 1991 for the vaccine stockpile, and such sums as may be necessary through 1995.

The Committee reaffirms support for the continued efforts of the National Vaccine Program operating through the Office of the As-

sistant Secretary for Health by extending its authorization through fiscal year 1995 for $34 million in fiscal year 1991 and such sums as may be necessary for the subsequent years.

V. Legislative History

The Centers for Disease Control Immunization Programs and the vaccine stockpile were authorized through fiscal year 1990 in P.L. 100-177, the Public Health Service Amendments of 1987. The National Vaccine Program was authorized through fiscal year 1991 in subtitle 1 of P.L. 99-660, the National Childhood Injury Act of 1986. S. 2629, the Immunization Program Reauthorization Act of 1990, was introduced May 15, 1990 by Senator Kennedy with Senators Hatch, Adams, and Dodd as cosponsors. The Labor and Human Resources Committee met to consider S. 2629 on May 16, 1990, and the bill was reported with an amendment by voice vote.

VI. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, June 19, 1990.

Hon. Edward M. Kennedy,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for S. 2629, the Immunization Program Reauthorization Act of 1990, as ordered reported by the Senate Committee on Labor and Human Resources on May 16, 1990.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

Robert F. Hale
(For Robert D. Reischauer).

Attachment.

1. Bill number: S. 2629.
2. Bill title: Immunization Program Reauthorization Act of 1990.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on May 16, 1990.
4. Bill purposes: To amend the Public Health Service Act to extend the immunization program for vaccine-preventable diseases, and for other purposes.
5. Estimated cost to the Federal Government:

[By fiscal years, in million of dollars]

	1991	1992	1993	1994	1995
Estimated authorization levels:					
Immunization grants	200	208	217	225	235
Vaccine supply	5	5	5	6	6
National vaccine program	0	4	4	5	5
Federal agency funds	0	31	32	34	35

[By fiscal years, in million of dollars]

	1991	1992	1993	1994	1995
New vaccine grants	(1)	(1)	(1)	(1)	(1)
Immunization demonstrations	(2)	(2)	(2)	(2)	(2)
Total estimated authorization levels [3]	205	249	259	269	280
Total estimated outlays [3]	109	187	235	260	273

[1] The cost of this provision, which depends on the approval of new vaccines, cannot be estimated. See the discussion below.
[2] The cost of this provisions depends on thue number of demonstrations supported. See the discussion below.
[3] Totals do not include the new vaccine grant or the immunization demonstrations provisions.

Details in the table may not add to totals due to rounding.

The cost of this bill fall within budget function 550.

Basis of estimate: S. 2629 would reauthorize federal funds to assist states and local areas to establish and maintain preventive health service programs that immunize individuals against vaccine-preventable diseases. The bill specifies an authorization level of $200 million in fiscal year 1991, and such sums as may be necessary in fiscal years 1992 to 1995 for this provision. CBO has estimated the 1992 to 1995 authorization levels by increasing the 1991 authorization by projected inflation.

The bill would authorize the Secretary of Health and Human Services to acquire and maintain a 6-month supply of vaccines. The 1991 authorization level was stated in the bill. CBO estimated the 1992 to 1995 authorization levels by increasing the 1991 authorization by projected inflation.

S. 2629 would reauthorize funding for the National Vaccine Program and for the federal agencies involved in the implementation of the program plan to research, develop, test, license, produce, and distribute vaccines. The bill specifies authorization amounts for fiscal year 1991, and such sums as may be necessary for fiscal years 1992 to 1995 for both these activities. Because fiscal year 1991 authorizations for the National Vaccine Program and for federal agency funding already exist in current law, no additional 1991 authorizations for this program would result due to the enactment of this bill. CBO estimated the 1992 to 1995 authorization levels for both of these provisions by increasing their respective 1991 authorization by projected inflation.

The bill provides an authorization of such sums as may be necessary to assist preventive health service programs to provide immunizations with vaccines approved and recommended for routine use after October 1, 1990. Because CBO cannot estimate how many vaccines might be approved, the costs of such vaccines, or the number of immunizations with these vaccines that might be provided through preventive health service programs, the estimate does not include a cost for this provision. Since 1987, only one new vaccine has been approved and recommended for routine use. If no new vaccines are approved after October 1, 1990, this provision would have no cost. This provision, however, could result in significant costs to the federal government if a new vaccine were approved for widespread use during this period.

In addition, the bill would authorize such sums as may be necessary to assist nonprofit entities to establish and support projects that develop, demonstrate, and evaluate methods for screening, and immunizing children up to age 2. Based on information provided by staff at the Centers for Disease Control, CBO estimates that each

demonstration project would cost about $1 million each fiscal year. The cost of this provision would depend on the number of demonstration projects supported.

This estimate assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

6. Estimated cost to State and local government: None.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Karen Graham.

10. Estimate approved by: C.G. Nuckols, for James L. Blum, Assistant Director for Budget Analysis.

VII. Regulatory Impact Statement

The Committee has determined that there will be minimal or no increase in regulatory burden imposed by this bill.

VIII. Section-by-Section Analysis

Section 1 of the bill provides that the act may be cited as the "Immunization Program Reauthorization Act of 1990".

Section 2 of the bill amends subparagraph (A) of section 317(j)(1) of the Public Health Service Act by authorizing $200 million for fiscal year 1991 for the CDC immunization program and grants to states, and such sum as may be necessary through fiscal year 1995. In addition, subparagraph (B) of the same section is amended to authorize such sums as may be necessary in fiscal years 1991 through 1995 for the immunizations program for the implementation of the use of a vaccine whose use is recommended by CDC after the date of the authorization.

Section 3 of the bill reauthorizes $5 million in fiscal year 1991, and such sums as may be necessary through fiscal year 1995, for the Director of the Centers of Disease Control to acquire and maintain a six-month supply of vaccines.

Section 4 amends section 2106 of the Public Health Service Act to reauthorize the National Vaccine Program through the Office of the Assistant Secretary of Health in the Department of Health and Human Services through fiscal year 1995. S. 2629 would reauthorize $4 million in fiscal year 1991, and such sums as may be necessary for 1992 to 1995, for the program's operations and responsibilities. In addition, $30 million would be authorized in fiscal year 1991, and such sums as may be necessary through fiscal year 1995, to enable the National Vaccine Program to make funds available to the Federal agencies involved in implementing the National Vaccine Plan to supplement the funds otherwise available to such agencies for activities under the plan.

Section 5 creates a new section, Section 317B, to provide for immunization demonstration projects to improve the vaccination levels of pre-school children under 24 months of age. The legislation would enable the Secretary to provide grants to public and nonprofit entities to establish and support projects for the development, demonstration, and evaluation of methods for the screening, referral, and immunization of children up to 24 months of age

against vaccine-preventable diseases, and to disseminate information regarding such methods to health and allied health professionals. The projects should emphasize methods of immunizing low-income, high risk children; screening, early intervention, and referral for immunization against childhood disease; measuring immunization levels to identify unvaccinated children and to strengthen surveillance in areas of low coverage; methods of tracking patient data with automated management information systems; and disseminating information to health and allied health professionals regarding immunizing children under 24 months of age. The legislation would authorize such sums as may be necessary for these immunization demonstration grants for fiscal years 1991 through 1993.

IX. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

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PROJECT GRANTS FOR PREVENTIVE HEALTH SERVICES

SEC. 317. (a) * * *

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(j)(1)(A) Except for grants for immunization programs the authorization of appropriations for which are established in subparagraph (B), for grants under subsections (a) and (k)(1) for preventive health service programs to immunize without change individuals against vaccine-preventable diseases, [there are authorized to be appropriated $94,000,000 for fiscal year 1988, and such sums as may be necessary for each of the fiscal years 1989 and 1990.] *there are authorized to be appropriated $200,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.* Not more than 10 percent of the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(1) for such fiscal year.

(B) For grants under subsection (a) for preventive health service programs for the provision without charge of immunizations with vaccines approved for use, and recommended for routine use, [after the date of the enactment of Public Health Service Amendments of 1987 [December 1, 1987], there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1988, 1989, and 1990.] *after October 1, 1990, there are authorized to be appropriated such sums as may be necessary.*

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART B—FEDERAL-STATE COOPERATION

IN GENERAL

SEC. 317A. * * *

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SEC. 317B. IMMUNIZATION DEMONSTRATION PROJECTS.

(a) GRANTS AND CONTRACTS.—

(1) IN GENERAL.—The Secretary, acting through the Centers for Disease Control, may make grants to public and private nonprofit entities and enter into contracts with private entities to establish and support projects for the development, demonstration and evaluation of methods for the screening, referral and immunization of children up to 24 months of age against vaccine-preventable diseases and for the dissemination of information concerning such methods to the health and allied health professions.

(2) ADDITIONAL RESOURCES.—The Secretary shall utilize additional resources to implement projects under this section that are designed to make more effective use of immunization grant resources to immunize at least 90 percent of all children by the time they reach 24 months of age.

(3) COORDINATION.—Activities conducted under projects receiving assistance under this section shall be coordinated with Federal, State, local and regional health and immunization entities that conduct activities under section 317.

(b) TYPE OF PROJECTS.—Projects that may receive assistance under this section shall include programs that emphasize the development and demonstration of new and improved—

(1) methods of immunizing children up to 2 years of age who are part of low-income and high-risk populations and geographic areas against vaccine-preventable diseases;

(2) methods of screening, early intervention, and referral for immunization against childhood disease;

(3) methods of measuring actual immunization coverage levels in defined populations to better identify unvaccinated children and to strengthen surveillance in areas of low coverage;

(4) methods of tracking patient data and recordkeeping with the use of an automated patient management information system; and

(5) methods of dissemination of information to health and allied health professionals and to low-income and high-risk populations concerning the importance of immunization of children up to 24 months of age at the earliest medically appropriate time, and concerning possible adverse reactions associated with immunizations.

(c) AUTHORIZATION OF APPROPRIATIONS.—In addition to such sums as are authorized to be appropriated under section 317, there

are authorized to be appropriated such additional sums as may be necessary for each of the fiscal years 1991 through 1993 for immunization demonstration project grants and contract under this section.

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AUTHORIZATIONS

SEC. 2106. (a) To carry out this subtitle other than section 2102(9) [there are authorized to be appropriated $2,000,000 for fiscal year 1987, $2,500,000 for fiscal year 1988, $3,000,000 for fiscal year 1989, $3,500,000 for fiscal year 1990, $4,000,000 for fiscal year 1991.] *there are authorized to be appropriated $4,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.*

(b) To carry out section 2102(9) [there are authorized to be appropriated $20,000,000 for fiscal year 1987, $22,500,000 for fiscal year 1988, $25,000,000 for fiscal year 1989, $27,500,000 for fiscal year 1990, $30,000,000 for fiscal year 1991.] *there are authorized to be appropriated $30,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.*

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